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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|--------------------------------|------------------|
| 10/080,053 | 02/21/2002 | Kenneth Houston | DR-332J | 6756 |
| 7590 Iandiorio & Teska 260 Bear Hill Road Waltham, MA 02451-1018 | | | EXAMINER BEISNER, WILLIAM H | |
| | | | ART UNIT 1744 | PAPER NUMBER |

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,053

Applicant(s)

HOUSTON ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 Aug. 2004 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 1 and 18, in view of the current claims language “a bio-sensor sealed in the vessel in the culture medium with the sample” raises issues of indefiniteness. First, it cannot be clearly determined if applicants intend the culture medium and sample to be considered as positively recited elements of the instantly claimed device. The preamble of the claim recites that the vessel is “for holding sample to be tested in a culture medium” while the body of the claim recites that the “bio-sensor is sealed in the vessel in the culture medium with the sample”. This language could be interpreted to mean that the vessel includes culture medium

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and a sample. Clarification and/or correction is requested. Also from applicants' remarks, it appears that applicants intend to claim a "sealed vessel", however, the instant claim language merely recites that the bio-sensor is sealed in the vessel. This language could be interpreted to include a bio-sensor sealed with respect to a bottom or side wall of a vessel while the vessel still includes top opening that is not sealed. Clarification and/or correction is requested.

The term "smart" in claims 1-18 is a relative term which renders the claim indefinite. The term "smart" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Note in the absence of further positively recited claim language defining the term "smart", the instant claims have been examined as though any prior art that meets the claim limitations recited in the body of the claim would inherently meet the preamble limitation of "A smart culture vessel".

Claims 2-17 are indefinite based merely on their dependencies from indefinite claim 1.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4-15, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Park et al. (Biosensors and Bioelectronics, Vol. 13).

With respect to claim 1, the reference of Park et al. discloses a culture vessel (f) that can hold culture medium and a sample. The vessel includes a bio-sensor having a coating (antibody) for attracting at least one pathogen (Salmonella). The device includes a detection circuit including an electrical connection between the bio-sensor and detection circuit for indicating the presence of pathogen on the bio-sensor (See Figure 1 and “2. Experimental” section). With respect to the claim limitation that the bio-sensor is sealed in the vessel, the reference of Park et al. discloses that the bio-sensor is held within a “dip holder with a plug”. This disclosure is interpreted to mean that the bio-sensor is held within the vessel in a sealed manner provided by the plug sealing the top opening of the vessel.

With respect to claims 4, 6-14, 17 and 18, the disclosed detection electronics are capable of driving the bio-sensor over a range of frequencies (resonant frequency which varies as pathogens bind to the surface of the bio-sensor) and are capable of detecting shifts in the frequency over time (See the “Experiment” and “Results and discussion” sections). As shown in Figures 3-5, the detection circuit is configured to “continuously” and “instantaneously” detect a shift in frequency due to the attached pathogen.

With respect to claim 5, the detection circuit is external to the vessel (See Figure 1).

With respect to claim 15, the system would inherently include electric wire for the electrical connection as is required for connecting the bio-sensor electrodes to the driving and sensing components shown in Figure 1.

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (Biosensors and Bioelectronics, Vol. 13).

The reference of Park et al. has been discussed above.

Claim 16 differs by specifically reciting that the electrical connection between the bio-sensor and detection circuit uses a cable.

The use of cables for providing the electrical connection of a plurality of wires between two electronic components is notoriously well known in the art.

As a result, it would have clearly been within the purview one having ordinary skill in the art to provide the electrical wires connecting the bio-sensor to the oscillator and analyzer in a cable format for the known and expected results of facilitating the connection of the bio-sensor to the detection circuitry.

10. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (Biosensors and Bioelectronics, Vol. 13) in view of Karube et al. (EP 0 215 669).

The reference of Park et al. has been discussed above.

Claims 2 and 3 differ by reciting that the biosensor for pathogen detection includes an array of biosensor elements with different coatings for attracting pathogens.

The reference of Karube et al. discloses that it is known in the art to provide an array of biosensor elements with respect to a single sensor device so as to simultaneously analyze a plurality of different analytes or pathogens (See page 7, lines 4-11, and Figure 16).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the primary reference so as to include an array of biosensor elements as suggested by the reference of Karube et al. for the known and expected result of providing an means recognized in the art for detecting a plurality of pathogens within a single sample.

Response to Arguments

11. Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection over the newly cited reference of Park et al. (Biosensors and Bioelectronics, Vol. 13).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The reference of Park et al. (Biosensors and Bioelectronics, Vol. 15) is cited as prior art that is similar to that of Part et al. employed in the prior art rejections above.

The reference of He et al. is cited as prior art that pertains to a bio-sensor that is sealed within a vessel (See Figure 1). The reference does not disclose that the bio-sensor includes a coating for attracting at least one pathogen.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB